PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

MORROW, Joy, D.
Smart & Biggar
900-55 Metcalfe Street
P.O. Box 2999
Station D
Ottawa, Ontario K1P 5Y6
CANADA

Date of mailing (day/month/year)
16 August 2000 (16.08.00)

Applicant's or agent's file reference
77813-6

IMPORTANT NOTIFICATION

International application No.
PCT/CA99/01224

International filing date (day/month/year)
22 December 1999 (22.12.99)

1. The following indications appeared on record concerning:

[X] the applicant [ ] the inventor [ ] the agent [ ] the common representative

Name and Address
CONNAUGHT LABORATORIES LIMITED
1755 Steeles Avenue West
Toronto, Ontario M2R 3T4
Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [X] the name [ ] the address [ ] the nationality [ ] the residence

Name and Address
AVENTIS PASTEUR LIMITED
1755 Steeles Avenue West
Toronto, Ontario M2R 3T4
Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[ ] the International Preliminary Examining Authority
[X] the designated Offices concerned
[ ] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
I. Britel

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

MORROW, Joy, D.
Smart & Biggar
900-55 Metcalfe Street
P.O. Box 2999
Station D
Ottawa, Ontario K1P 5Y6
CANADA

Date of mailing (day/month/year)
20 March 2001 (20.03.01)

Applicant's or agent's file reference
77813-6

IMPORTANT NOTIFICATION

International application No.
PCT/CA99/01224

International filing date (day/month/year)
22 December 1999 (22.12.99)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address
DUNN, Pamela
Apartment 703
370 Kaneff Crescent
Mississauga, Ontario L5A 4B8
Canada

State of Nationality: GB
State of Residence: CA
Telephone No.:
Facsimile No.:
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2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
DUNN, Pamela
97 Rosebury Lane
Woodbridge, Ontario L4L 3Z1
Canada

State of Nationality: GB
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Athina Nickitas-Etienne
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

MORROW, Joy, D.
Smart & Biggar
900-55 Metcalfe Street
P.O. Box 2999
Station D
Ottawa, Ontario K1P 5Y6
CANADA

Date of mailing (day/month/year) 20 March 2001 (20.03.01)	
Applicant's or agent's file reference 77813-6	**IMPORTANT NOTIFICATION**
International application No. PCT/CA99/01224	**International filing date** (day/month/year) 22 December 1999 (22.12.99)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address	State of Nationality	State of Residence
WANG, Joe 48 29th Street Etobicoke, Ontario M8W 3A8 Canada	CA	CA
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address	State of Nationality	State of Residence
WANG, Joe 51 Aspenwood Drive Toronto, Ontario M2H 2E8 Canada	CA	CA
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Athina Nickitas-Etienne

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

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PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

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MORROW, Joy, D.
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Ottawa, Ontario K1P 5Y6
CANADA

Date of mailing (day/month/year)
20 March 2001 (20.03.01)

Applicant's or agent's file reference
77813-6

IMPORTANT NOTIFICATION

International application No.
PCT/CA99/01224

International filing date (day/month/year)
22 December 1999 (22.12.99)

1. The following indications appeared on record concerning:

[X] the applicant [X] the inventor [ ] the agent [ ] the common representative

Name and Address
MURDIN, Andrew, D.
146 Rhodes Circle
Newmarket, Ontario L3X 1V2
Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
MURDIN, Andrew, D.
11 Forest Hill Drive
Richmond Hill, Ontario L4B 3C2
Canada

State of Nationality: CA
State of Residence: CA
Telephone No.:
Facsimile No.:
Teleprinter No.:

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

Authorized officer
Athina Nickitas-Etienne
Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

MORROW, Joy D.
SMART & BIGGAR
900-55 Metcalfe Street
P.O. Box 2999, Station D
Ottawa, Ontario K1P 5Y6
CANADA

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	30.03.2001

Applicant's or agent's file reference	IMPORTANT NOTIFICATION
77813-6	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/01224	22/12/1999	28/12/1998

Applicant
CONNAUGHT LABORATORIES LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Emslander, S Tel.+49 89 2399-8718

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
77813-6		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA99/01224	22/12/1999	28/12/1998
International Patent Classification (IPC) or national classification and IPC C07K14/295		
Applicant CONNAUGHT LABORATORIES LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25/07/2000	30.03.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Stolz, B Telephone No. +49 89 2399 8416

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/01224

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1-6,8-52	filed with the demand			
7,7a	as received on	06/02/2001	with letter of	06/02/2001

Claims, No.:

1-43	as received on	06/02/2001	with letter of	06/02/2001

Drawings, sheets:

1/11-11/11 filed with the demand

Sequence listing part of the description, pages:

6, as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☒ contained in the international application in written form.
   - ☒ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence

listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2-6, 8-19, 22-43
	No:	Claims	1, 7, 20, 21
Inventive step (IS)	Yes:	Claims	2-6, 8-19, 22-41
	No:	Claims	1, 7, 20, 21, 42, 43
Industrial applicability (IA)	Yes:	Claims	1-43
	No:	Claims	

2. Citations and explanations
   see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. Reasoned statement

1.1. The application describes an ADP/ATP translocase from Chlamydia pneumoniae and its use in eliciting a protective effect against C. pneumonia infection in mice.

The requested amendments to the description and the claims do not contravene Art. 34(2)(b) PCT.

1.2. Novelty (Art. 33(2) PCT

Claim 1 includes nucleic acid molecules comprising a nucleic acid sequence encoding an immunogenic peptide fragment of at least 20 consecutive amino acids of Seq ID no. 2. A putative ADP/ATP translocase from C. trachomatis has been described by Stephens et al. (Science 1998, and XP002133122 (collectively D1)). The molecule identified in D1 has 79% sequence identity at the amino acid level and comprises three exactly matching stretches of 22, 28 and 33 amino acids, respectively (positions 159-180, 392-419, 421-453). The nucleic acid sequence of D1 can thus be described as comprising nucleic acid sequences encoding the required immunogenic fragments. Consequently, claims 1, 7, 20 and 21 lack novelty.

1.3. Inventive step (Art. 33(3) PCT)

Claims 42 and 43 refer to isolated ATP/ADP translocases from Chlamydia and Chlamydia pneumoniae, respectively. The IPEA is of the opinion, that since the existence of ATP/ADP translocases in Chlamydia was known from Hatch et al., 1982, and from D1, the cloning of any further generically defined ATP/ADP translocase from Chlamydia sp., e.g. from C. psitacci, did not require inventive skills.

The use of Chlamydia DNA encoding major outer membrane proteins (MOMPs) for vaccination was generically disclosed in WO98/02546 (D2) and a specific example using DNA from C. trachomatis was shown to work. D2 also generically refers to the use of MOMPs from C. pneumoniae (p. 4, line 9). The instant application cites the prior art as having identified many antigenic determinants on

C. pneumoniae to be conserved across all Chlamydia but some to be C. pneumonia specific (p. 7, lines 19 to 25). Thus, while there is a generic teaching on how to obtain immune protection and while there seem to be a number of unidentified candidate epitopes, there is no indication in the cited prior art which would lead the person of skill to the claimed molecule and its uses in an obvious way. In view of the contribution of the present application, i.e. the demonstration of a molecule from C. pneumoniae suitable for immune protection, the remaining claims are considered to be inventive.

2. Certain observations

2.1. Claims 18 and 19 refer to nucleic acid probes and primers, respectively, being at least 75% similar to the molecule of Seq. ID no. 1 or to an undefined homolog thereof. While it is possible to determine if a molecule is 75% identical to Seq. ID 1, it is impossible to know what subject matter should be covered by the unspecified homolog. Moreover, it is questionable if a molecule of 5 nucleotides in length with 75% identity to a fragment of Seq. ID no. 1 (i.e. having 4 identical bases), is new in each and every case. The same argument applies to homologs thereof.

2.2. Claims 42 and 43 do not define the claimed invention as required by Art. 6 PCT but merely define the result to be achieved. In other words, they paraphrase the underlying technical problem. The existence of ADP/ATP translocases in Chlamydia was known (e.g. Hatch et al., 1982).

surfaces can also exert a protective effect (Cotter *et al.* (1995) Infection and Immunity 63:4704).

Antigenic variation within the species *C. pneumoniae* is not well documented due to insufficient genetic information, though variation is expected to exist based on *C. trachomatis*. Serovars of *C. trachomatis* are defined on the basis of antigenic variation in the major outer membrane protein (MOMP), but published *C. pneumoniae* MOMP gene sequences show no variation between several diverse isolates of the organism (Campbell *et al* (1990) Infection and Immunity 58:93; McCafferty *et al* (1995) Infection and Immunity 63:2387-9; Knudsen *et al* (1996) Third Meeting of the European Society for Chlamydia Research, Vienna). The gene encoding a 76 kDa antigen has been cloned from a single strain of *C. pneumoniae* and the sequence published (Perez Melgosa *et al.*, Infect. Immun. 1994. 62:880). An operon encoding the 9 kDa and 60 kDa cyteine-rich outer membrane protein genes has been described (Watson *et al.*, Nucleic Acids Res (1990) 18:5299; Watson *et al.*, Microbiology (1995) 141:2489). Many antigens recognized by immune sera to *C. pneumoniae* are conserved across all chlamydiae, but 98 kDa, 76 kDa and several other proteins may be *C. pneumoniae*-specific (Perez Melgosa *et al.*, Infect. Immun. 1994. 62:880; Melgosa *et al.*, FEMS Microbiol Lett (1993) 112 :199;, Campbell *et al.*, J Clin Microbiol (1990) 28 :1261; Iijima *et al.*, J Clin Microbiol (1994) 32:583). An assessment of the number and relative frequency of any *C. pneumoniae* serotypes, and the defining antigens, is not yet possible. The entire genome sequence of *C. pneumoniae* strain CWL-029 is now known (http://chlamydia-www.berkeley.edu:4231/) and as further sequences become available a better understanding of antigenic variation may be gained.

Many antigens recognised by immune sera to *C. pneumoniae* are conserved across all chlamydiae, but 98kDa, 76 kDa and 54 kDa proteins appear to be *C. pneumoniae*-specific

CLAIMS

1. A nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any of:

(a) SEQ ID No: 2;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified to improve its immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

2. A nucleic acid molecule comprising a nucleic acid sequence selected from any of:

(a) SEQ ID No: 1;

(b) a sequence which encodes a polypeptide encoded by SEQ ID No: 1;

(c) a sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (a) and (b); and

(d) a sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to the polypeptides encoded by SEQ ID No: 1.

3. A nucleic acid molecule comprising a nucleic acid sequence which is anti-sense to the nucleic acid molecule of claim 1.

4. A nucleic acid molecule comprising a nucleic acid sequence which encodes a fusion protein, said fusion protein comprising a polypeptide encoded by a nucleic acid molecule according to claim 1 and an additional polypeptide.

5. The nucleic acid molecule of claim 4 wherein the additional polypeptide is a heterologous signal peptide.

6. The nucleic acid molecule of claim 4 wherein the additional polypeptide has adjuvant activity.

7. A nucleic acid molecule according to any one of claims 1 to 6, operatively linked to one or more expression control sequences.

8. A vaccine comprising at least one first nucleic acid according to any one of claims 1, 2, and 4 to 7 and a vaccine vector wherein each first nucleic acid is expressed as a polypeptide, the vaccine optionally comprising a second nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide expressed by said first nucleic acid.

9. The vaccine of claim 8 wherein the second nucleic acid encodes an additional *Chlamydia* polypeptide.

10. A pharmaceutical composition comprising a nucleic acid according to any one of claims 1 to 7 and a pharmaceutically acceptable carrier.

11. A pharmaceutical composition comprising a vaccine according to claim 8 or 9 and a pharmaceutically acceptable carrier.

12. A unicellular host transformed with the nucleic acid molecule of claim 7.

13. A nucleic acid probe of 5 to 100 nucleotides which hybridizes under stringent conditions to the nucleic acid

molecule of SEQ ID No: 1, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule.

14. A primer of 10 to 40 nucleotides which hybridizes under stringent conditions to the nucleic acid molecules of SEQ ID No: 1, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule.

15. A polypeptide encoded by a nucleic acid sequence according to any one of claims 1, 2 and 4 to 7.

16. A polypeptide comprising an amino acid sequence selected from any of:

(a) SEQ ID No: 2;

(b) an immunogenic fragment comprising at least 12 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified to improve its immunogenicity, wherein said modified polypeptide is at least 75% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

17. A fusion polypeptide comprising a polypeptide of claim 15 or 16 and an additional polypeptide.

18. The fusion polypeptide of claim 17 wherein the additional polypeptide is a heterologous signal peptide.

19. The fusion protein of claim 17 wherein the additional polypeptide has adjuvant activity.

20. A method for producing a polypeptide of claim 15 or 16, comprising the step of culturing a unicellular host according to claim 12.

21. An antibody against the polypeptide of any one of claims 15 to 19.

22. A vaccine comprising at least one first polypeptide according to any one of claims 15 to 19 and a pharmaceutically acceptable carrier, optionally comprising a second polypeptide which enhances the immune response to the first polypeptide.

23. The vaccine of claim 22 wherein the second polypeptide comprises an additional *Chlamydia* polypeptide.

24. A pharmaceutical composition comprising a polypeptide according to any one of claims 15 to 19 and a pharmaceutically acceptable carrier.

25. A pharmaceutical composition comprising a vaccine according to claim 22 or 23 and a pharmaceutically acceptable carrier.

26. A pharmaceutical composition comprising an antibody according to claim 21 and a pharmaceutically acceptable carrier.

27. A method for preventing or treating *Chlamydia* infection using:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the vaccine of any one of claims 8, 9, 22 and 23;

(c) the pharmaceutical composition of any one of claims 10, 11, 24 to 26;

(d) the polypeptide of any one of claims 15 to 19; or

(e) the antibody of claim 21.

28. A method of detecting *Chlamydia* infection comprising the step of assaying a body fluid of a mammal to be tested, with a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of any one of claims 15 to 19; and

(c) the antibody of claim 21.

29. A diagnostic kit comprising instructions for use and a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of any one of claims 15 to 19; and

(c) the antibody of claim 21.

30. A method for identifying a polypeptide of claims 15 to 19 which induces an immune response effective to prevent or lessen the severity of *Chlamydia* infection in a mammal previously immunized with polypeptide, comprising the steps of:

(a) immunizing a mouse with the polypeptide; and

(b) inoculating the immunized mouse with *Chlamydia;*

wherein the polypeptide which prevents or lessens the severity of *Chlamydia* infection in the immunized mouse compared to a non-immunized control mouse is identified.

31. Expression plasmid pCAI640.

32. A nucleic acid molecule of SEQ ID NO. 3 or 4.

33. An ATP/ADP translocase from *Chlamydia*.

34. An ATP/ADP translocase from *Chlamydia pneumoniae*

surfaces can also exert a protective effect (Cotter *et al.* (1995) Infection and Immunity 63:4704).

Antigenic variation within the species C. *pneumoniae* is not well documented due to insufficient genetic information, though variation is expected to exist based on C. *trachomatis*. Serovars of C. *trachomatis* are defined on the basis of antigenic variation in the major outer membrane protein (MOMP), but published C. *pneumoniae* MOMP gene sequences show no variation between several diverse isolates of the organism (Campbell *et al* (1990) Infection and Immunity 58:93; McCafferty *et al* (1995) Infection and Immunity 63:2387-9; Gaydos *et al.* (1992) Infection and Immunity 60(12):5319-5323). The gene encoding a 76 kDa antigen has been cloned from a single strain of C. *pneumoniae* and the sequence published (Perez Melgosa et al., Infect. Immun. 1994. 62:880). An operon encoding the 9 kDa and 60 kDa cyteine-rich outer membrane protein genes has been described (Watson et al., Nucleic Acids Res (1990) 18:5299; Watson et al., Microbiology (1995) 141:2489). Many antigens recognized by immune sera to C. *pneumoniae* are conserved across all chlamydiae, but 98 kDa, 76 kDa and several other proteins may be C. *pneumoniae*-specific (Perez Melgosa *et al.*, Infect. Immun. 1994. 62:880; Melgosa *et al.*, FEMS Microbiol Lett (1993) 112:199; Campbell *et al.*, J. Clin Microbiol (1990) 28:1261; Iijima *et al.*, J. Clin Microbiol (1994) 32:583). An assessment of the number and relative frequency of any C. *pneumoniae* serotypes, and the defining antigens, is not yet possible. The entire genome sequence of C. *pneumoniae* strain CWL-029 is now known (http://chlamydia-www.berkeley.edu:4231/) and as further sequences become available a better understanding of antigenic variation may be gained.

Many antigens recognised by immune sera to C. *pneumoniae* are conserved across all chlamydiae, but 98 kDa, 76 kDa and 54 kDa proteins appear to be C. *pneumoniae*-specific

CLAIMS:

1. A nucleic acid molecule comprising a nucleic acid sequence which encodes a polypeptide selected from any of:

(a) SEQ ID No: 2;

(b) an immunogenic fragment comprising at least 20 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 80% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

2. A nucleic acid molecule comprising a nucleic acid sequence selected from any of:

(a) SEQ ID No: 1;

(b) a sequence which encodes a polypeptide encoded by SEQ ID No: 1;

(c) a sequence comprising at least 60 consecutive nucleotides from any one of the nucleic acid sequences of (a) and (b); and

(d) a sequence which encodes a polypeptide which is at least 80% identical in amino acid sequence to the polypeptide encoded by SEQ ID No: 1.

3. A nucleic acid molecule comprising a nucleic acid sequence which is anti-sense to the nucleic acid molecule of claim 1 or 2.

4. A nucleic acid molecule comprising a nucleic acid sequence which encodes a fusion protein, said fusion protein

comprising a polypeptide encoded by a nucleic acid molecule according to claim 1 and a second polypeptide.

5. The nucleic acid molecule of claim 4 wherein the second polypeptide is a heterologous signal peptide.

6. The nucleic acid molecule of claim 4 wherein the second polypeptide has adjuvant activity.

7. A nucleic acid molecule according to any one of claims 1 to 6, operatively linked to one or more expression control sequences.

8. A vaccine comprising a vaccine vector and at least one first nucleic acid selected from any of:

(i) SEQ ID No: 1;

(ii) a nucleic acid sequence which encodes a polypeptide encoded by SEQ ID No: 1;

(iii) a nucleic acid sequence comprising at least 38 consecutive nucleotides from any one of the nucleic acid sequences of (i) and (ii);

(iv) a nucleic acid sequence which encodes a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by SEQ ID No: 1;

(v) a nucleic acid sequence which encodes a polypeptide whose sequence is set forth in SEQ ID No: 2;

(vi) a nucleic acid sequence which encodes an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID No:2; and

(vii) a nucleic acid sequence which encodes a polypeptide as defined in (v) or an immunogenic fragment as

defined in (vi) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (v) or the corresponding fragment of (vi);

wherein each first nucleic acid is capable of being expressed and wherein the vaccine optionally comprises a second nucleic acid encoding and capable of expressing an additional polypeptide which enhances the immune response to the polypeptide expressed by the first nucleic acid.

9. A vaccine comprising a vaccine vector and at least one first nucleic acid encoding a fusion protein, wherein the fusion protein comprises:

(a) a first polypeptide selected from any of:

(i) a polypeptide encoded by SEQ ID No: 1;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from SEQ ID No: 1;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by SEQ ID No: 1;

(iv) a polypeptide whose sequence is set forth in SEQ ID No: 2;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID No:2; and

(vi) a polypeptide as defined (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to

the corresponding polypeptide of (iv) or the corresponding fragment of (v); and

(b) a second polypeptide;

wherein each first nucleic acid is capable of being expressed and wherein the vaccine optionally comprises a second nucleic acid encoding and capable of expressing an additional polypeptide which enhances the immune response to the first polypeptide.

10. The vaccine of claim 9 wherein the second polypeptide is a heterologous signal peptide.

11. The vaccine of claim 9 wherein the second polypeptide has adjuvant activity.

12. The vaccine of any one of claims 8 to 11 wherein wherein each first nucleic acid is operatively linked to one or more expression control sequences.

13. A vaccine comprising at least one first nucleic acid according to any one of claims 1, 2, and 4 to 7 and a vaccine vector wherein each first nucleic acid is expressed as a polypeptide, the vaccine optionally comprising a second nucleic acid encoding an additional polypeptide which enhances the immune response to the polypeptide expressed by said first nucleic acid.

14. The vaccine of any one of claims 8 to 13 wherein the second nucleic acid encodes an additional *Chlamydia* polypeptide.

15. A pharmaceutical composition comprising a nucleic acid according to any one of claims 1 to 7 and a pharmaceutically acceptable carrier.

16. A pharmaceutical composition comprising a vaccine according to any one of claims 8 to 14 and a pharmaceutically acceptable carrier.

17. A unicellular host transformed with the nucleic acid molecule of claim 7.

18. A nucleic acid probe of 5 to 100 nucleotides which are at least 75% similar to the nucleic acid molecule of SEQ ID No: 1, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule.

19. A primer of 10 to 40 nucleotides which which are at least 75% similar to the nucleic acid molecules of SEQ ID No: 1, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule.

20. A polypeptide encoded by a nucleic acid sequence according to any one of claims 1, 2 and 4 to 7.

21. A polypeptide comprising an amino acid sequence selected from any of:

(a) SEQ ID No: 2;

(b) an immunogenic fragment comprising at least 20 consecutive amino acids from a polypeptide of (a); and

(c) a polypeptide of (a) or (b) which has been modified without loss of immunogenicity, wherein said modified polypeptide is at least 80% identical in amino acid sequence to the corresponding polypeptide of (a) or (b).

22. A fusion protein comprising a polypeptide of claim 20 or 21 and a second polypeptide.

23. The fusion protein of claim 22 wherein the second polypeptide is a heterologous signal peptide.

24. The fusion protein of claim 22 wherein the second polypeptide has adjuvant activity.

25. A method for producing a polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24, comprising the step of culturing a unicellular host of claim 17.

26. An antibody against the polypeptide of claim 20 or 21, or against a fusion protein of any one of claims 22 to 24.

27. A vaccine comprising at least one first polypeptide selected from any of:

(i) a polypeptide encoded by SEQ ID No: 1;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from SEQ ID No: 1;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by SEQ ID No: 1;

(iv) a polypeptide whose sequence is set forth in SEQ ID No: 2;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID No:2; and

(vi) a polypeptide as defined in (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (iv) or the corresponding fragment of (v);

wherein the vaccine optionally comprises an additional polypeptide which enhances the immune response to the first polypeptide.

28. A vaccine comprising at least one fusion protein, wherein the fusion protein comprises:

(a) a first polypeptide selected from any of:

(i) a polypeptide encoded by SEQ ID No: 1;

(ii) a polypeptide encoded by a nucleic acid sequence comprising at least 38 consecutive nucleotides from SEQ ID No: 1;

(iii) a polypeptide which is at least 75% identical in amino acid sequence to the polypeptide encoded by SEQ ID No: 1;

(iv) a polypeptide whose sequence is set forth in SEQ ID No: 2;

(v) an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID No:2; and

(vi) a polypeptide as defined (iv) or an immunogenic fragment as defined in (v) which has been modified without loss of immunogenicity, wherein said modified polypeptide or fragment is at least 75% identical in amino acid sequence to the corresponding polypeptide of (iv) or the corresponding fragment of (v); and

(b) a second polypeptide;

wherein the vaccine optionally comprises an additional polypeptide which enhances the immune response to the first polypeptide.

29. The vaccine of claim 28 wherein the second polypeptide is a heterologous signal peptide.

30. The vaccine of claim 28 wherein the second polypeptide has adjuvant activity.

31. A vaccine comprising at least one first polypeptide according to any one of claims 20 to 24, optionally comprising an additional polypeptide which enhances the immune response to the first polypeptide.

32. The vaccine of any one of claims 27 to 31 wherein the additional polypeptide comprises a *Chlamydia* polypeptide.

33. A pharmaceutical composition comprising a polypeptide according to any one of claims 20 to 24 and a pharmaceutically acceptable carrier.

34. A pharmaceutical composition comprising a vaccine according to any one of claims 27 to 32 and a pharmaceutically acceptable carrier.

35. A pharmaceutical composition comprising an antibody according to claim 26 and a pharmaceutically acceptable carrier.

36. A method for preventing or treating *Chlamydia* infection using:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the vaccine of any one of claims 8 to 14 and 27 to 32;

(c) the pharmaceutical composition of any one of claims 15, 16 and 33 to 35;

(d) the polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24; or

(e) the antibody of claim 26.

37. A method of detecting *Chlamydia* infection comprising the step of assaying a body fluid of a mammal to be tested, with a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24; and

(c) the antibody of claim 26.

38. A diagnostic kit comprising instructions for use and a component selected from any one of:

(a) the nucleic acid of any one of claims 1 to 7;

(b) the polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24; and

(c) the antibody of claim 26.

39. A method for identifying a polypeptide of claim 20 or 21, or a fusion protein of any one of claims 22 to 24 which induces an immune response effective to prevent or lessen the severity of *Chlamydia* infection in a mammal previously immunized with polypeptide, comprising the steps of:

(a) immunizing a mouse with the polypeptide or fusion protein; and

(b) inoculating the immunized mouse with *Chlamydia;*

wherein the polypeptide or fusion protein which prevents or lessens the severity of *Chlamydia* infection in the

immunized mouse compared to a non-immunized control mouse is identified.

40. Expression plasmid pCAI764 as shown in Figure 3.

41. A nucleic acid molecule of SEQ ID NO. 3 or 4.

42. An isolated ATP/ADP translocase from a *Chlamydia* species other than *Chlamydia trachomatis*.

43. An isolated ATP/ADP translocase from *Chlamydia pneumoniae*.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
77813-6		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CA 99/01224	22/12/1999	28/12/1998
Applicant		
CONNAUGHT LABORATORIES LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [X] contained in the international application in written form.

   [X] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 4

   [X] as suggested by the applicant.

   [ ] None of the figures.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

Internat[illegible] Application No
PCT/CA 99/01224

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C07K14/295 C12N15/31 C12N15/62 A61K48/00 C12N5/10
C12Q1/68 C07K16/12 A61K39/118 A61K38/16 C07K19/00
C12P21/00 G01N33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C07K A61K C12Q G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE GENEMBL [Online] 22 July 1998 (1998-07-22) STEPHENS ET AL: "Chlamydia trachomatis section 8 of 87 of the complete genome" XP002133122	1-12, 15-31,33
Y	Accession AE001281 -& STEPHENS ET AL: "Genome Sequence of an Obligate Intracellular Pathogen of Humans: Chlamydia trachomatis" SCIENCE, vol. 282, 23 October 1998 (1998-10-23), pages 754-759, XP002104802 page 755, middle column, paragraph 3 --- -/--	8-11,27, 31

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 March 2000	06 APR. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	ALCONADA RODRIG.., A

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Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) page 10, line 24 -page 15, line 2 examples 1-4 ---	8-11,27, 31
X	HATCH T P ET AL: "Adenine nucleotide and lysine transport in Chlamydia psittaci." JOURNAL OF BACTERIOLOGY, (1982 MAY) 150 (2) 662-70. , XP000864461 abstract page 663, right-hand column, last paragraph -page 664, right-hand column, paragraph 1 page 668, left-hand column, paragraph 1 table 1 figures 1,2 ---	33,34
P,X	WO 99 27105 A (GRIFFAIS REMY ;GENSET (FR)) 3 June 1999 (1999-06-03) page 5, line 6 -page 6, line 20 page 13, line 34 -page 14, line 3 page 46, line 4-14 page 51, line 6 -page 54, line 28 page 56, line 30 -page 57, line 2 page 60, line 12-25 page 62, line 10 -page 66, line 4 page 65, line 1-8 page 68, line 25-32 page 69, line 7 -page 70, line 22 page 104 SEQ ID NO:6850 SEQ ID NO:369 ---	1-12, 15-34
P,X	DATABASE GENEMBL [Online] 15 March 1999 (1999-03-15) KALMAN ET AL: "Chlamydia pneumoniae section 35 of 103 of the complete genome" XP002133123 Accession AE001619 -& KALMAN ET AL: "Comparative Genomes of Chlamydia pneumoniae and C. trachomatis" NATURE GENETICS, vol. 21, April 1999 (1999-04), pages 385-389, XP000853883 page 387, left-hand column --- -/--	1-7,12, 15-34

2

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	DATABASE GENEMBL [Online] 23 March 1999 (1999-03-23) NEUHAUS,E.: "Chlamydia trachomatis npt1 gene" XP002133124 Accession TAJ10586 -& TJADEN ET AL: "Two nucleotide transport proteins in Chlamydia trachomatis, one for net nucleoside triphosphate uptake and the other for transport of energy" J.BACTERIOL, vol. 181, no. 4, February 1999 (1999-02), pages 1196-1202, XP002133121 -----	1-7,12, 15-31,33

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/[redacted] 99/01224

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802546 A	22-01-1998	AU 3431497 A	09-02-1998
		CA 2259595 A	22-01-1998
		EP 0915978 A	19-05-1999
WO 9927105 A	03-06-1999	AU 1170299 A	15-06-1999

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 99/01224

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C07K14/295 C12N15/31 C12N15/62 A61K48/00 C12N5/10
C12Q1/68 C07K16/12 A61K39/118 A61K38/16 C07K19/00
C12P21/00 G01N33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C07K A61K C12Q G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	Accession AE001281 -& STEPHENS ET AL: "Genome Sequence of an Obligate Intracellular Pathogen of Humans: Chlamydia trachomatis" SCIENCE, vol. 282, 23 October 1998 (1998-10-23), pages 754-759, XP002104802 page 755, middle column, paragraph 3 --- -/--	8-11,27, 31

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[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 March 2000	06 APR. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	ALCONADA RODRIG.., A

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) page 10, line 24 -page 15, line 2 examples 1-4	8-11,27, 31
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P,X	WO 99 27105 A (GRIFFAIS REMY ;GENSET (FR)) 3 June 1999 (1999-06-03) page 5, line 6 -page 6, line 20 page 13, line 34 -page 14, line 3 page 46, line 4-14 page 51, line 6 -page 54, line 28 page 56, line 30 -page 57, line 2 page 60, line 12-25 page 62, line 10 -page 66, line 4 page 65, line 1-8 page 68, line 25-32 page 69, line 7 -page 70, line 22 page 104 SEQ ID NO:6850 SEQ ID NO:369	1-12, 15-34
P,X	DATABASE GENEMBL [Online] 15 March 1999 (1999-03-15) KALMAN ET AL: "Chlamydia pneumoniae section 35 of 103 of the complete genome" XP002133123 Accession AE001619 -& KALMAN ET AL: "Comparative Genomes of Chlamydia pneumoniae and C. trachomatis" NATURE GENETICS, vol. 21, April 1999 (1999-04), pages 385-389, XP000853883 page 387, left-hand column	1-7,12, 15-34

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA 99/01224

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 27, as far as concerning a method of treatment, and claim 30 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [X] Claims Nos.: 13,14
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 13,14

Present claims 13 and 14 relate to an extremely large number of possible compounds, namely, primer which hybridizes under stringent conditions to the nucleic acid sequences of SEQ ID NO:1, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is not to be found, however, for any of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has not been carried out for those claims.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 99/01224

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802546 A	22-01-1998	AU 3431497 A	09-02-1998
		CA 2259595 A	22-01-1998
		EP 0915978 A	19-05-1999
WO 9927105 A	03-06-1999	AU 1170299 A	15-06-1999

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
77813-6		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/CA 99/01224	22/12/1999	28/12/1998
Applicant		
CONNAUGHT LABORATORIES LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

[X] contained in the international application in written form.

[X] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readble form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

[X] the text is approved as submitted by the applicant.

[ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 4

[X] as suggested by the applicant.

[ ] None of the figures.

[ ] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 99/01224

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C07K14/295 C12N15/31 C12N15/62 A61K48/00 C12N5/10
C12Q1/68 C07K16/12 A61K39/118 A61K38/16 C07K19/00
C12P21/00 G01N33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12N C07K A61K C12Q G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	Accession AE001281 -& STEPHENS ET AL: "Genome Sequence of an Obligate Intracellular Pathogen of Humans: Chlamydia trachomatis" SCIENCE, vol. 282, 23 October 1998 (1998-10-23), pages 754-759, XP002104802 page 755, middle column, paragraph 3 ---	8-11,27, 31
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 March 2000	06. APR. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	ALCONADA RODRIG.., A

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Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 98 02546 A (UNIV MANITOBA ;BRUNHAM ROBERT C (CA)) 22 January 1998 (1998-01-22) page 10, line 24 -page 15, line 2 examples 1-4	8-11,27, 31
X	HATCH T P ET AL: "Adenine nucleotide and lysine transport in Chlamydia psittaci." JOURNAL OF BACTERIOLOGY, (1982 MAY) 150 (2) 662-70. , XP000864461 abstract page 663, right-hand column, last paragraph -page 664, right-hand column, paragraph 1 page 668, left-hand column, paragraph 1 table 1 figures 1,2	33,34
P,X	WO 99 27105 A (GRIFFAIS REMY ;GENSET (FR)) 3 June 1999 (1999-06-03) page 5, line 6 -page 6, line 20 page 13, line 34 -page 14, line 3 page 46, line 4-14 page 51, line 6 -page 54, line 28 page 56, line 30 -page 57, line 2 page 60, line 12-25 page 62, line 10 -page 66, line 4 page 65, line 1-8 page 68, line 25-32 page 69, line 7 -page 70, line 22 page 104 SEQ ID NO:6850 SEQ ID NO:369	1-12, 15-34
P,X	DATABASE GENEMBL [Online] 15 March 1999 (1999-03-15) KALMAN ET AL: "Chlamydia pneumoniae section 35 of 103 of the complete genome" XP002133123 Accession AE001619 -& KALMAN ET AL: "Comparative Genomes of Chlamydia pneumoniae and C. trachomatis" NATURE GENETICS, vol. 21, April 1999 (1999-04), pages 385-389, XP000853883 page 387, left-hand column	1-7,12, 15-34

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	DATABASE GENEMBL [Online] 23 March 1999 (1999-03-23) NEUHAUS,E.: "Chlamydia trachomatis npt1 gene" XP002133124 Accession TAJ10586 -& TJADEN ET AL: "Two nucleotide transport proteins in Chlamydia trachomatis, one for net nucleoside triphosphate uptake and the other for transport of energy" J.BACTERIOL, vol. 181, no. 4, February 1999 (1999-02), pages 1196-1202, XP002133121 -----	1-7,12, 15-31,33

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 99/01224

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9802546 A	22-01-1998	AU 3431497 A	09-02-1998
		CA 2259595 A	22-01-1998
		EP 0915978 A	19-05-1999
WO 9927105 A	03-06-1999	AU 1170299 A	15-06-1999

INTERNATIONAL SEARCH REPORT

national application No.
PCT/CA 99/01224

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 27, as far as concerning a method of treatment, and claim 30 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [X] Claims Nos.: 13,14
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

see FURTHER INFORMATION sheet PCT/ISA/210

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 13,14

Present claims 13 and 14 relate to an extremely large number of possible compounds, namely, primer which hybridizes under stringent conditions to the nucleic acid sequences of SEQ ID NO:1, or to a homolog or complementary or anti-sense sequence of said nucleic acid molecule. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is not to be found, however, for any of the compounds claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has not been carried out for those claims.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.